

EFFECTIVE DATE NOTE: At 63 FR 5252, Feb. 2, 1998, §314.300 was amended in the introductory text of paragraph (b)(6) by adding a new sentence after the first sentence, effective Feb. 2, 1999.

### Subpart G—Miscellaneous Provisions

SOURCE: 50 FR 7493, Feb. 22, 1985, unless otherwise noted. Redesignated at 57 FR 17983, Apr. 28, 1992.

#### §314.410 Imports and exports of new drugs and antibiotics.

(a) *Imports.* (1) A new drug or an antibiotic may be imported into the United States if: (i) It is the subject of an approved application under this part or, in the case of an antibiotic not exempt from certification under part 433, it is also certified or released; or (ii) it complies with the regulations pertaining to investigational new drugs under part 312; and it complies with the general regulations pertaining to imports under subpart E of part 1.

(2) A drug substance intended for use in the manufacture, processing, or repackaging of a new drug may be imported into the United States if it complies with the labeling exemption in §201.122 pertaining to shipments of drug substances in domestic commerce.

(b) *Exports.* (1) A new drug or an antibiotic may be exported if it is the subject of an approved application under this part, and, in the case of an antibiotic, it is certified or released, or it complies with the regulations pertaining to investigational new drugs under part 312.

(2) A new drug substance that is covered by an application approved under this part for use in the manufacture of an approved drug product may be exported by the applicant or any person listed as a supplier in the approved application, provided the drug substance intended for export meets the specifications of, and is shipped with a copy of the labeling required for, the approved drug product.

(3) An antibiotic drug product or drug substance that is subject to certification under section 507 of the act, but which has not been certified or released, may be exported under section 801(e) of the act if it meets the following conditions:

(i) It meets the specifications of the foreign purchaser;

(ii) It is not in conflict with the laws of the country to which it is intended for export;

(iii) It is labeled on the outside of the shipping package that it is intended for export; and

(iv) It is not sold or offered for sale in the United States.

#### §314.420 Drug master files.

(a) A drug master file is a submission of information to the Food and Drug Administration by a person (the drug master file holder) who intends it to be used for one of the following purposes: To permit the holder to incorporate the information by reference when the holder submits an investigational new drug application under part 312 or submits an application or an abbreviated application or an amendment or supplement to them under this part, or to permit the holder to authorize other persons to rely on the information to support a submission to FDA without the holder having to disclose the information to the person. FDA ordinarily neither independently reviews drug master files nor approves or disapproves submissions to a drug master file. Instead, the agency customarily reviews the information only in the context of an application under part 312 or this part. A drug master file may contain information of the kind required for any submission to the agency, including information about the following:

(1) Manufacturing site, facilities, operating procedures, and personnel (because an FDA on-site inspection of a foreign drug manufacturing facility presents unique problems of planning and travel not presented by an inspection of a domestic manufacturing facility, this information is only recommended for foreign manufacturing establishments);

(2) Drug substance, drug substance intermediate, and materials used in their preparation, or drug product;

(3) Packaging materials;

(4) Excipient, colorant, flavor, essence, or materials used in their preparation;